



THE TISSUE ISSUE: Ethical and Legal Issues in Biorepository Research

Sponsored by the Arizona Biomedical Research Commission, the Flinn Foundation and the Arizona Hospital and Healthcare Association

Program Agenda

8:00 – 9:00 a.m.	Registration and networking breakfast
9:00 – 9:30 a.m.	Welcome and Introductions Dawn C. Schroeder, D.D.S., MA Executive Director, Arizona Biomedical Research Commission William A. Read, Ph.D. Vice President for Research & Technology, Flinn Foundation Kristen B. Rosati, J.D. Partner, Coppersmith Gordon Schermer & Brockelman PLC
9:30 – 10:15 a.m.	Keynote Speaker: The Power of Biorepositories for Research Anna D. Barker, Ph.D. Deputy Director for Advanced Technologies and Strategic Partnerships, National Cancer Institute
10:15 – 10:30 a.m.	Break
10:30 – 11:15 a.m.	Biorepositories in Arizona: Our Local Landscape Robert J. Penny, M.D., Ph.D. Chairman and CEO, Molecular Profiling Institute; Chief Operating Officer, Chief Medical Officer, Executive Director expO, International Genomics Consortium Joseph Rogers, Ph.D. President and Senior Scientist, Sun Health Research Institute Anil Prasad, M.D. Assistant Professor of Clinical Pathology, University of Arizona Health Science Center Joan Shapiro, Ph.D. V.P. Research and Development, St. Joseph's Hospital and Medical Center
11:15 – 11:45 a.m.	IRB Review of Biorepository Research <ul style="list-style-type: none">• Addressing regulatory compliance at three levels: the specimen source, the biorepository, and the provision of biospecimens for research protocols• Evaluating when IRB review is required and whose IRB should perform the review• Proposed guidance for IRB review of biorepository specimen collection, storage and dissemination P. Pearl O'Rourke, M.D. Director of Human Research Affairs, Partners HealthCare Systems, Inc.

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11:45 a.m. – 1:00 p.m. Lunch and Program

Keynote Speaker: National Efforts to Encourage Biobanking

Greg Simon, J.D.

President, FasterCures/The Center for Accelerating Medical Solutions

FasterCures, whose mission is to identify and implement solutions to accelerate the process of discovery and clinical development of new therapies, has established "BioBank Central," a Web site containing information about the logistical, technical, ethical, financial, intellectual property, and IT challenges facing biobanks and news about biorepositories and their role in research and drug development.

1:00 – 2:30 p.m.

Protecting Donors and Their Communities

- Seeking informed consent from donors
- Dealing with donor requests for withdrawal of tissue
- Communication of research findings to donors
- Ensuring donor privacy: HIPAA and Common Rule regulatory requirements
- Involving American Indian participants and communities

Edward B. Goldman, J.D.

Associate Vice President and Deputy General Counsel, Office of the General Counsel, University of Michigan Health System

Rebecca Dahl, Ph.D.

Director, Human Subjects Protection Program, University of Arizona

Donald K. Warne, M.D., M.P.H.

Clinical Professor Indian Legal Program, Arizona State University Sandra Day O'Connor College of Law

Kristen B. Rosati, J.D.

Partner, Coppersmith Gordon Schermer & Brockelman PLC

2:30 – 2:45 p.m.

Break

2:45 – 4:15 p.m.

The Business of Biospecimens: Tissue Transfer

- Drafting tissue transfer policies
- Drafting Material Transfer Agreements, Clinical Trial Agreements, and other agreements to transfer tissue
- Understanding issues for non-profit and tax-exempt organizations
- Recognizing and handling the intellectual property issues
- Dealing with potential ownership issues

Gary Marchant, J.D., Ph.D., M.P.P.

Executive Director and Faculty Fellow, Center for the Study of Law, Science, and Technology; Lincoln Professor of Emerging Technologies, Law and Ethics, Arizona State University Sandra Day O'Connor College of Law

Manoja Lecamwasam, Ph.D.

Director, Intellectual Property and Innovation, St. Joseph's Hospital and Medical Center

Catherine Horrigan, J.D.

Of Counsel, Research, Cleveland Clinic Foundation

4:15 – 4:30 p.m.

Next Steps: Convening the Biorepository Policy Development Committee

- Open invitation to participate in development of a template policy, informed consent document, HIPAA authorization form, and training module on biorepository research
- Timeline and first meeting of committee

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